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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,204	06/22/2001	Moshe Fleshner-Barak	1662/53002	7559
26646	7590	03/23/2006		
KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004			EXAMINER FUBARA, BLESSING M	
			ART UNIT 1618	PAPER NUMBER

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/887,204	FLESHNER-BARAK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 March 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 90-96 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 90-96 is/are allowed.
- 6) Claim(s) 90-96 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                        |                                                                             |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____                                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|                                                                                                                        | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

Examiner acknowledges receipt of Notice of Appeal and amendment after final filed

3/3/06. Claims 90-96 are pending.

1. The indicated allowability of claims 90-96 is withdrawn in view of the newly discovered reference(s) to Burnside. Rejections based on the newly cited reference(s) follow.
2. The finality of the rejection of the last Office action is withdrawn in view of the cancellation of the rejected claims.

### ***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 90-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burnside et al. (US 6,322,819) in view of Swanson et al. (US 4,326,525).

Burnside discloses multiple pulsed dose drug delivery system (abstract) comprising a core (column 6, lines 52-56) that includes one or more amphetamine salts coated with immediate release coating and one or more amphetamine salts that are covered with enteric coating (column 3, lines 25-48; column 4), and additives, the additives are binders, disintegration agent, filling agent, surfactant, solubilizers and stabilizers (column 6, line 64; column 7, lines 1, 6, 11, 14 and 18). Hydroxypropyl methylcellulose is an example of a binder additive (column 6, lines 63-67); cross-linked carboxymethylcellulose (AC-DISOL), sodium starch glycolate (EXPLOTAB), crosslinked polyvinylpyrrolidone (PLASDONE XL) are examples of disintegration agents (column 7, lines 1-5); mannitol, lactose, polyethylene glycol are few of the fillers in Burnside

(column 7, lines 6-10); PLURONIC is a surfactant in Burnside (column 7, lines 10-13); methylphenidate is specifically disclosed as an amphetamine derivative (column 7, lines 48-55).

The cross-linked carboxymethylcellulose (AC-DISOL), sodium starch glycolate (EXPLOTAB), crosslinked polyvinylpyrrolidone (PLASDONE XL) meet the limitation of the claimed disintegration agents.

Burnside discloses a composition comprising disintegration agent and methylphenidate and the composition is multi-particulate with some cores coated with enteric coating material and others coated with immediate release coating materials. The formulation of Burnside does not contain tannic acid or tannin or gallotannic acid.

However, Swanson discloses a dosage form containing methylphenidate (column 7, line 16), tannic acid (column 7, line 44; column 8, line 16). Thus, Swanson is relied upon for disclosing methylphenidate formulation that comprises tannic acid.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the methylphenidate multi-core dosage form according to Burnside. One having ordinary skill in the art would have been motivated to include tannic acid in the formulation of Burnside with the expectation of producing and providing multiple pulsed dose of amphetamine salts and specifically methylphenidate.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara  
Patent Examiner  
Tech. Center 1600

